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(54) **SYSTEMS AND METHODS FOR VALVULAR REGURGITATION DETECTION**

(75) Inventors: **Abhilash Patangay**, Little Canada, MN (US); **Krzysztof Z. Siejko**, Maple Grove, MN (US)

(73) Assignee: **Cardiac Pacemakers, Inc.**, St. Paul, MN (US)

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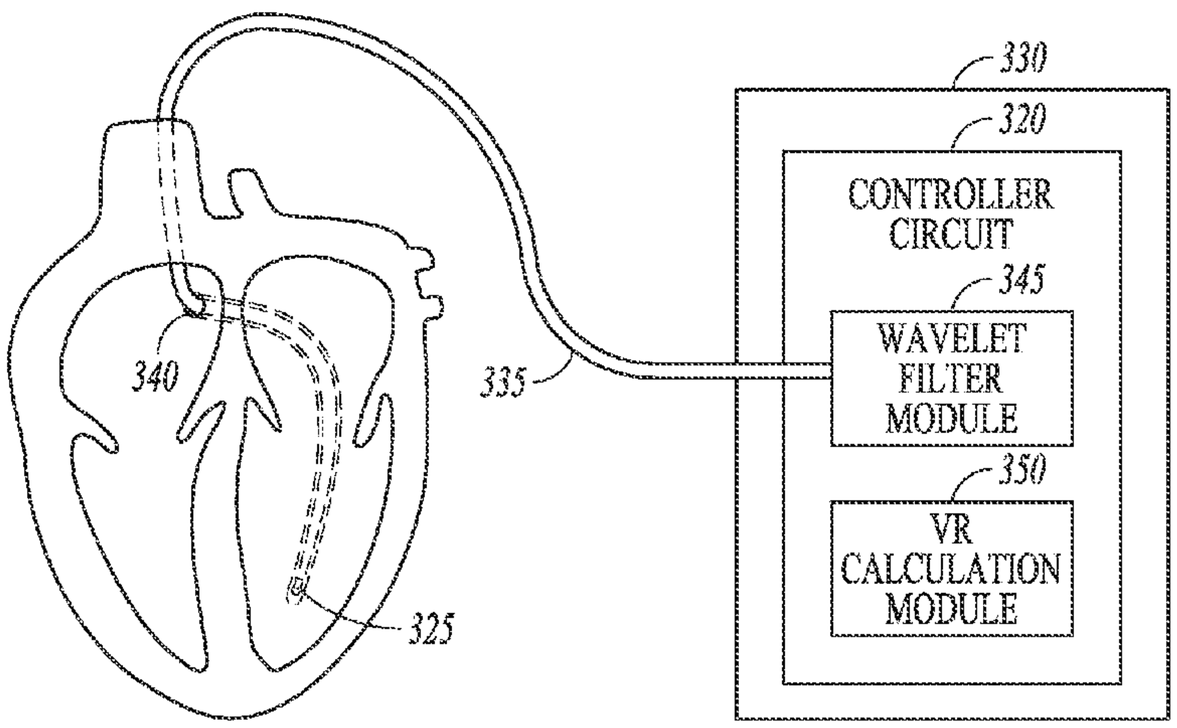
Primary Examiner — Niketa Patel
Assistant Examiner — Alyssa M Alter
(74) *Attorney, Agent, or Firm* — Schwegman, Lundberg & Woessner, P.A.

(57) **ABSTRACT**

A system comprising an implantable medical device (IMD). The IMD includes an implantable sensor operable to produce an electrical signal representative of mechanical activity of a heart of a subject and a controller circuit coupled to the sensor. The controller circuit includes a wavelet filter module and a valvular regurgitation (VR) calculation module. The wavelet filter module is configured to extract signal energy information from the electrical signal. The energy information includes variation of signal amplitude with frequency and time. The VR calculation module is configured to calculate a measurement of VR for one or more heartbeats using the energy information.

35 Claims, 8 Drawing Sheets



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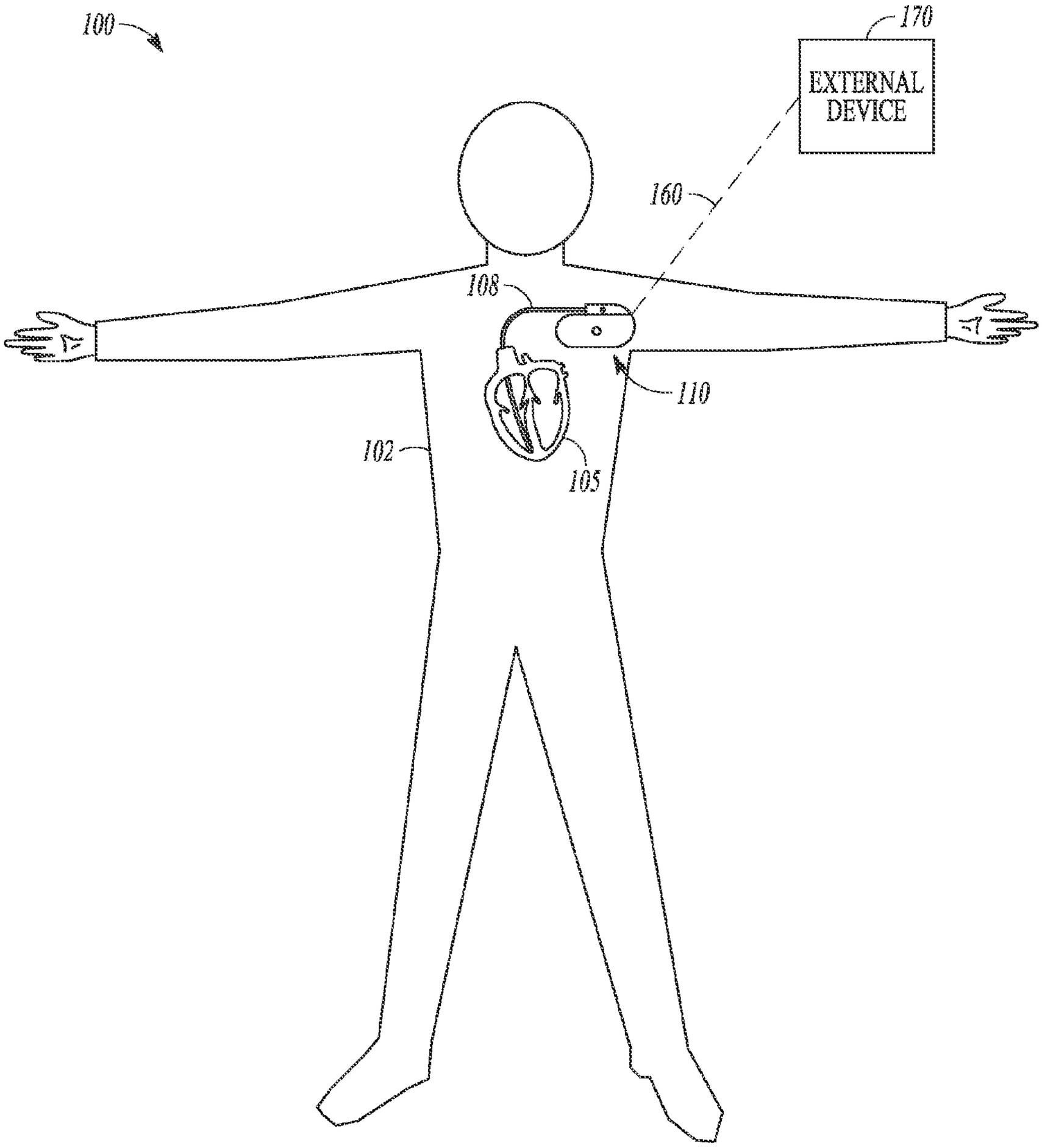
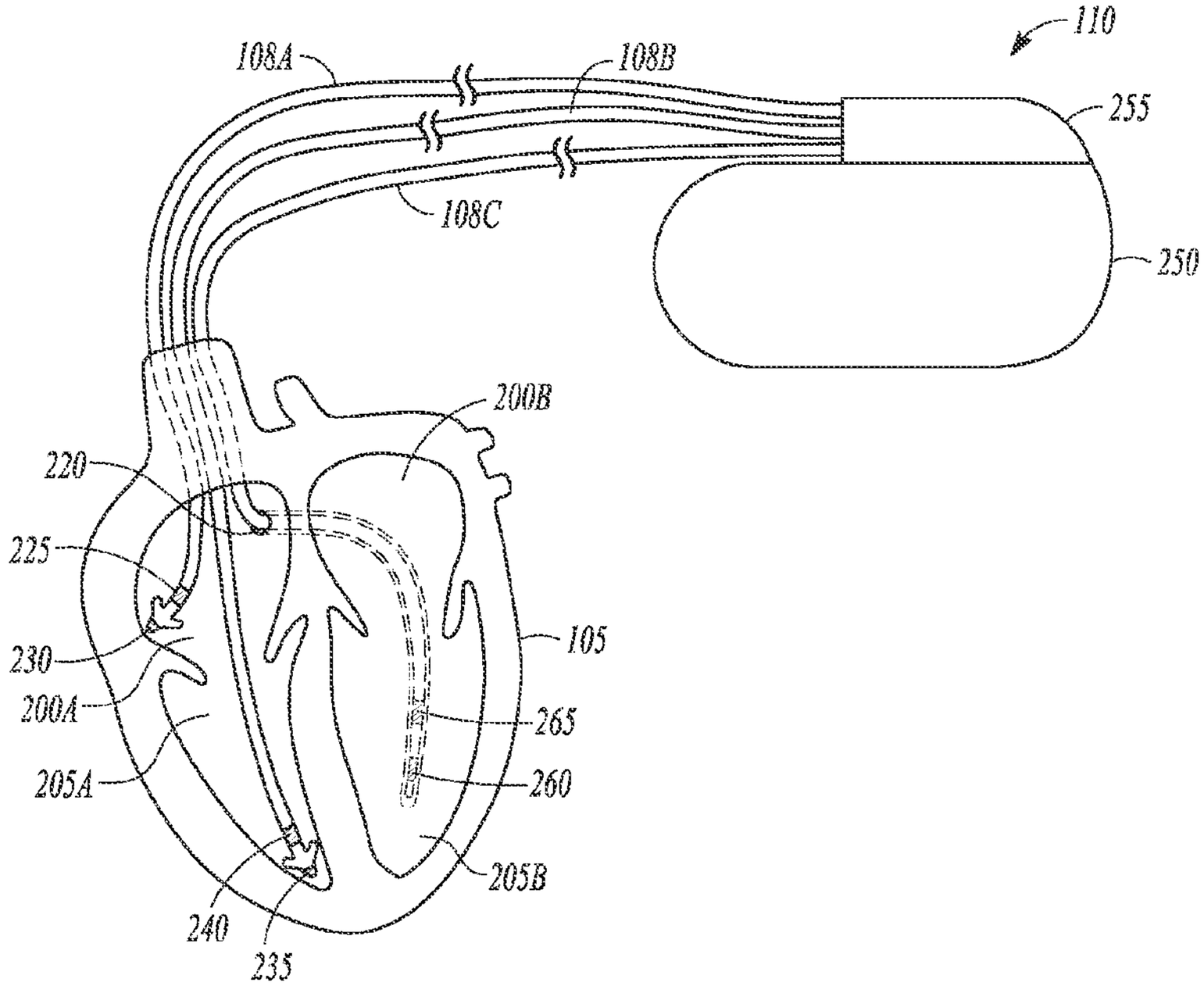


FIG. 1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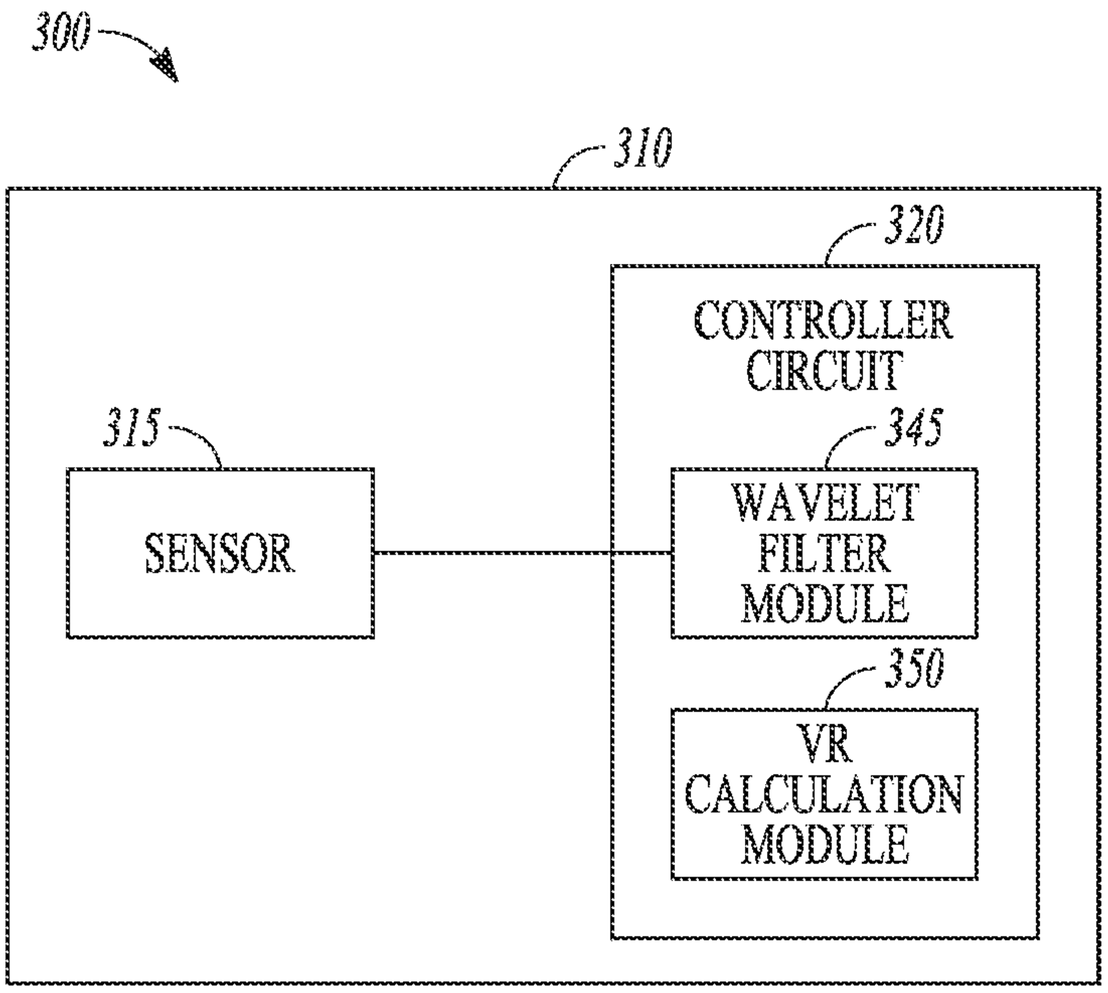
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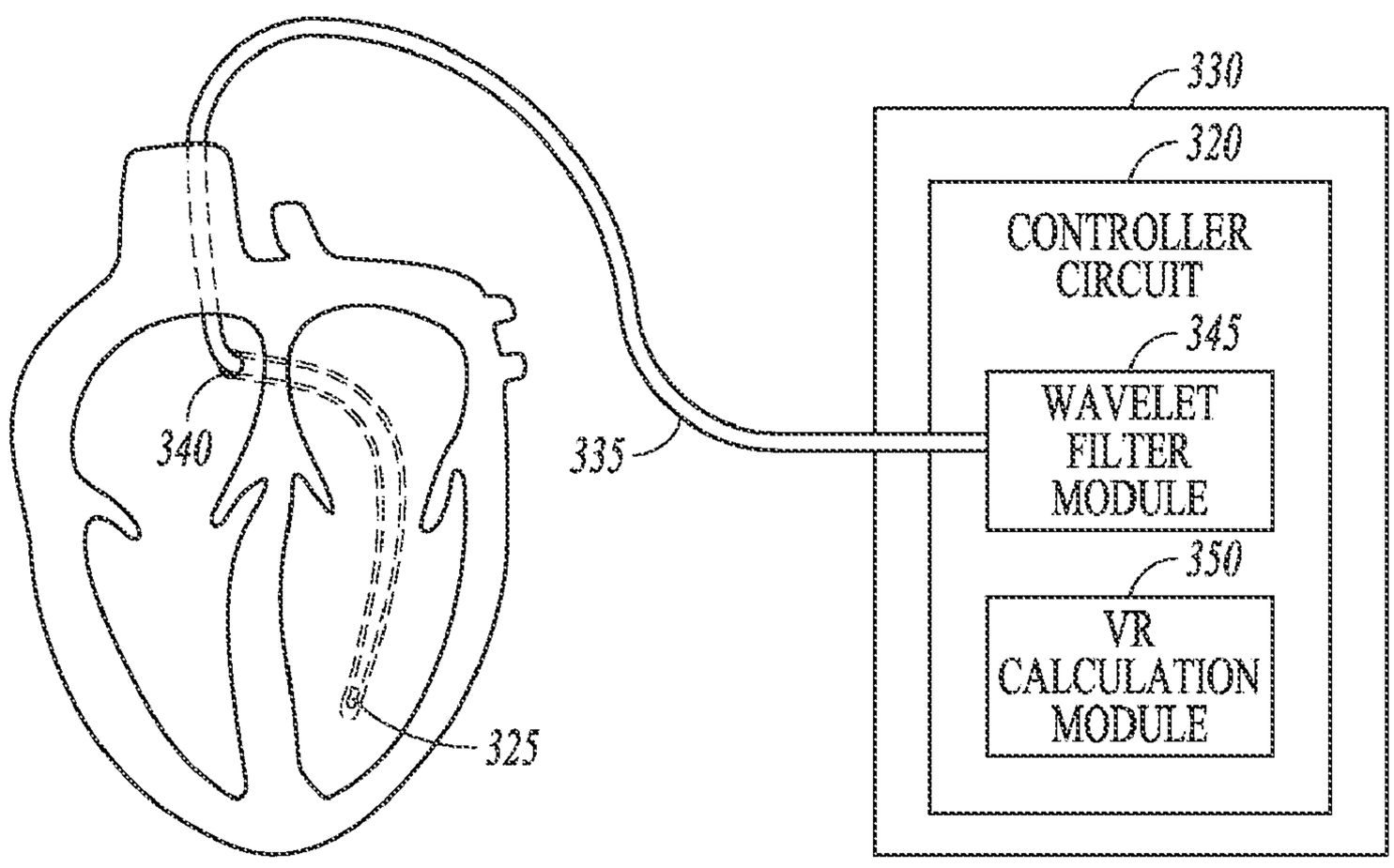
VR CALCULATION MODULE

FIG. 3A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WAVELET FILTER MODULE
350
VR CALCULATION MODULE
335
340
325

FIG. 3B

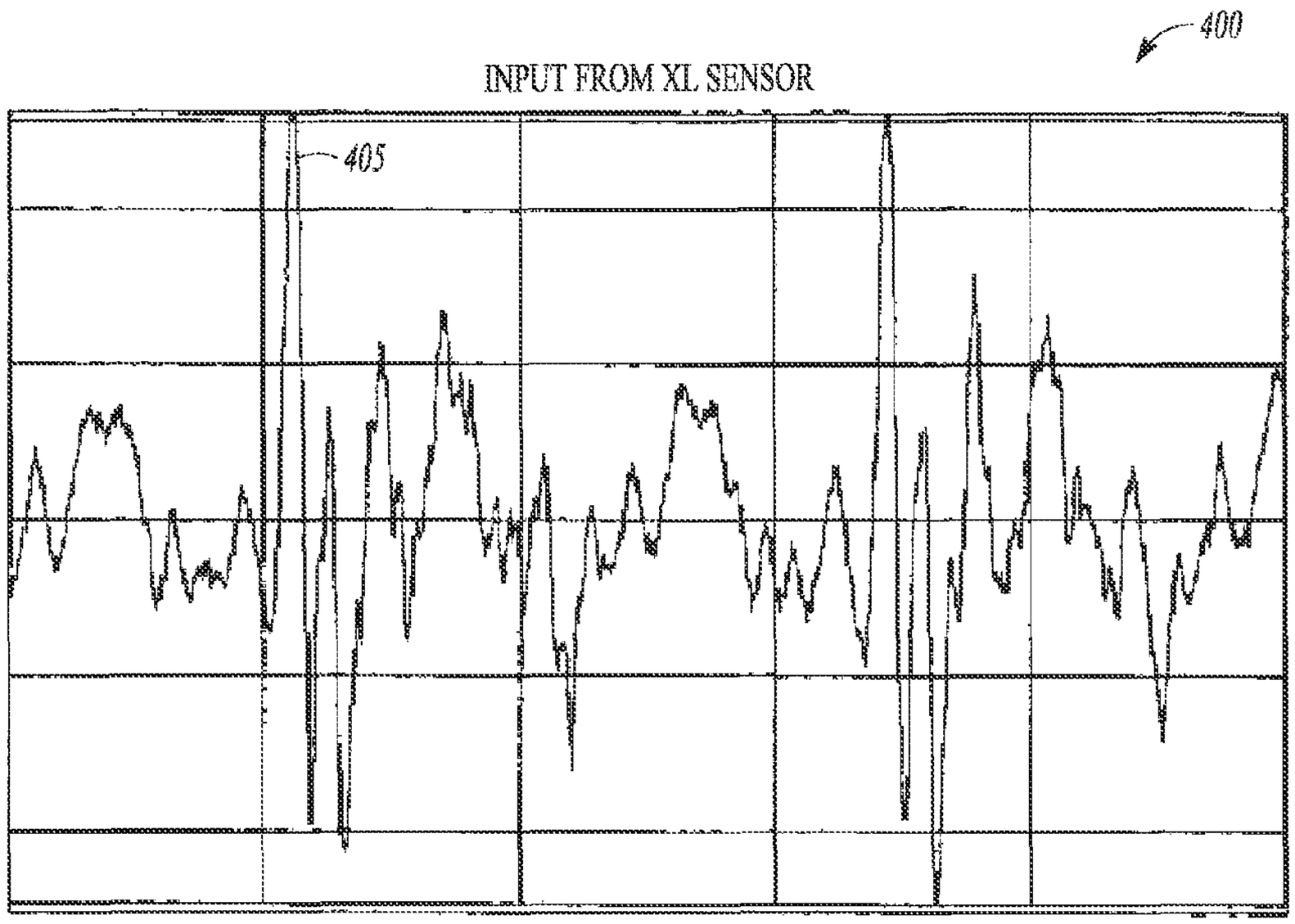

FIG. 4

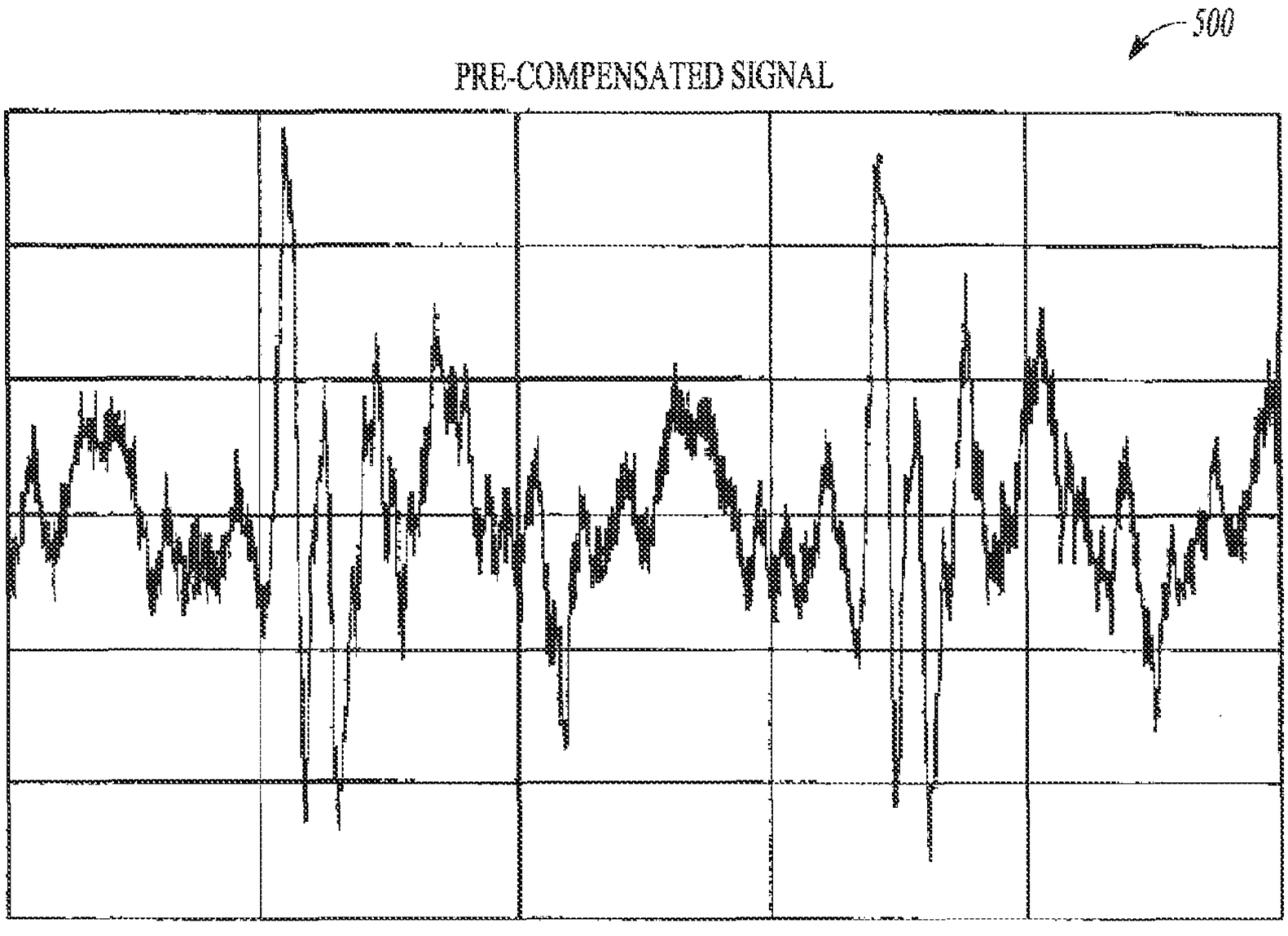

FIG. 5

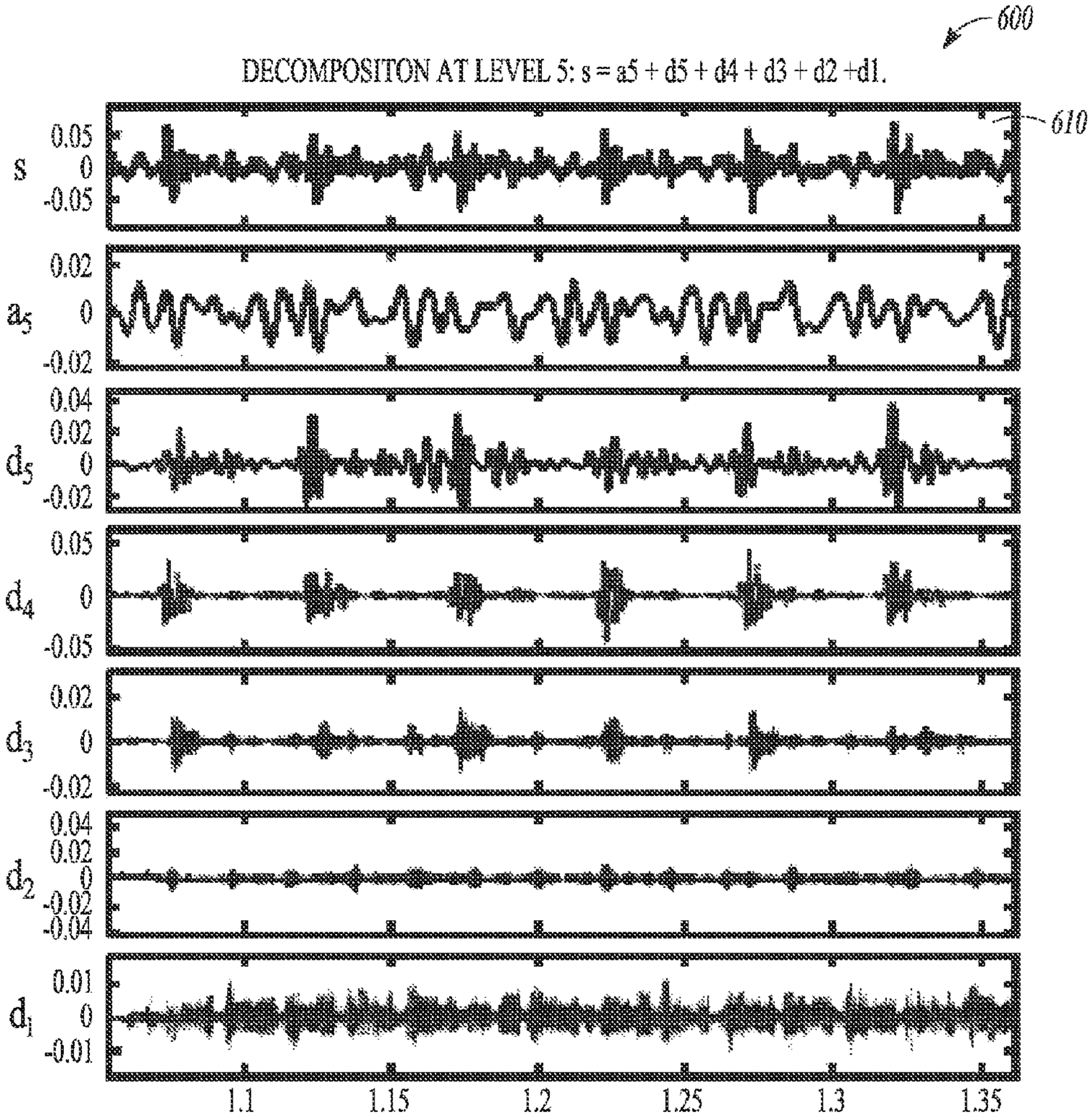
600
DECOMPOSITON AT LEVEL 5: s = a5 + d5 + d4 + d3 + d2 +d1.
610
s
0.05
0
-0.05
a5
0.02
0
-0.02
d5
0.04
0.02
0
-0.02
d4
0.05
0
-0.05
d3
0.02
0
-0.02
d2
0.04
0.02
0
-0.02
-0.04
d1
0.01
0
-0.01
1.1
1.15
1.2
1.25
1.3
1.35

FIG. 6

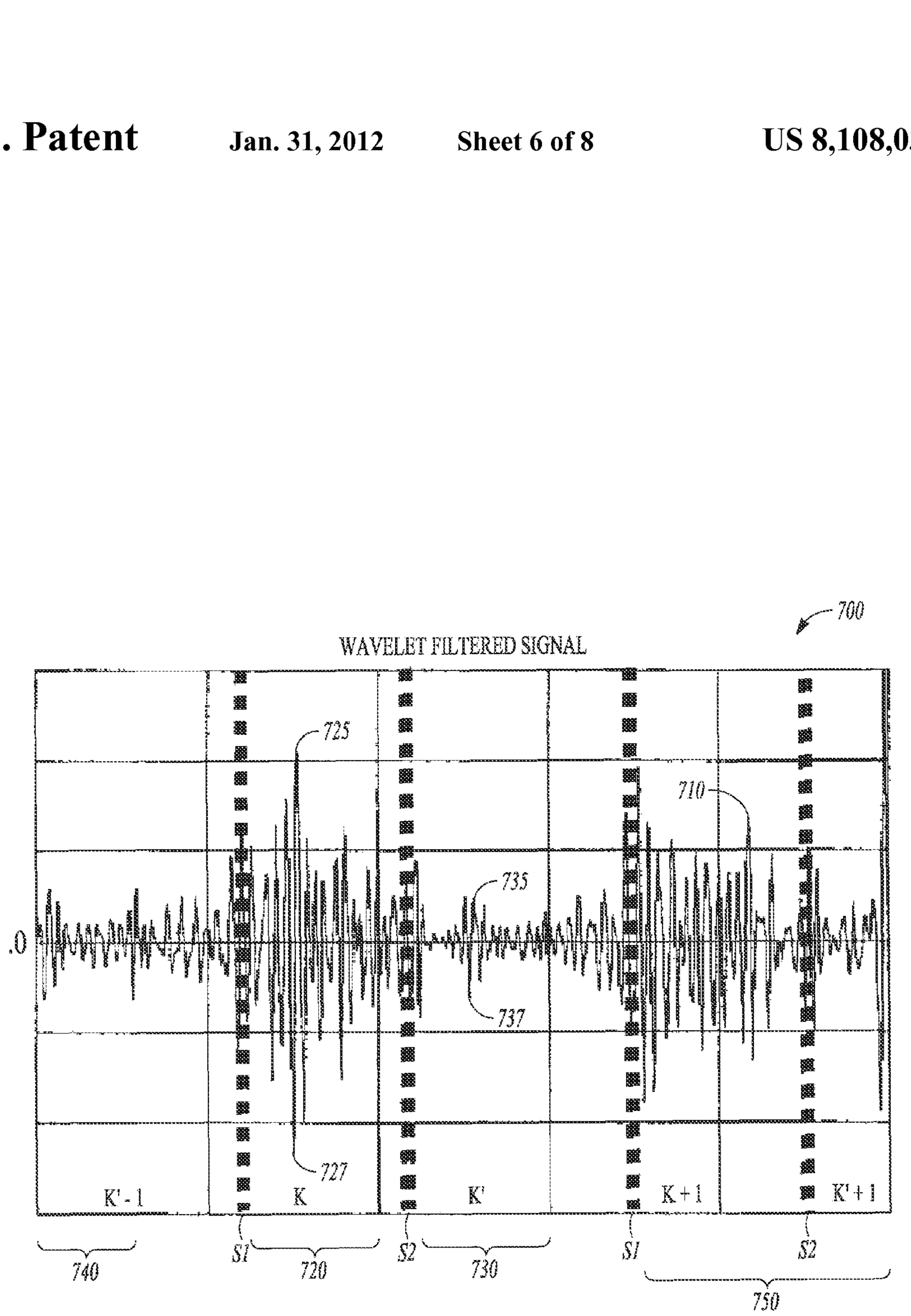
700
WAVELET FILTERED SIGNAL
725
710
735
737
727
0
K' - 1
K
K'
K + 1
K' + 1
S1
S2
S1
S2
740
720
730
750

FIG. 7

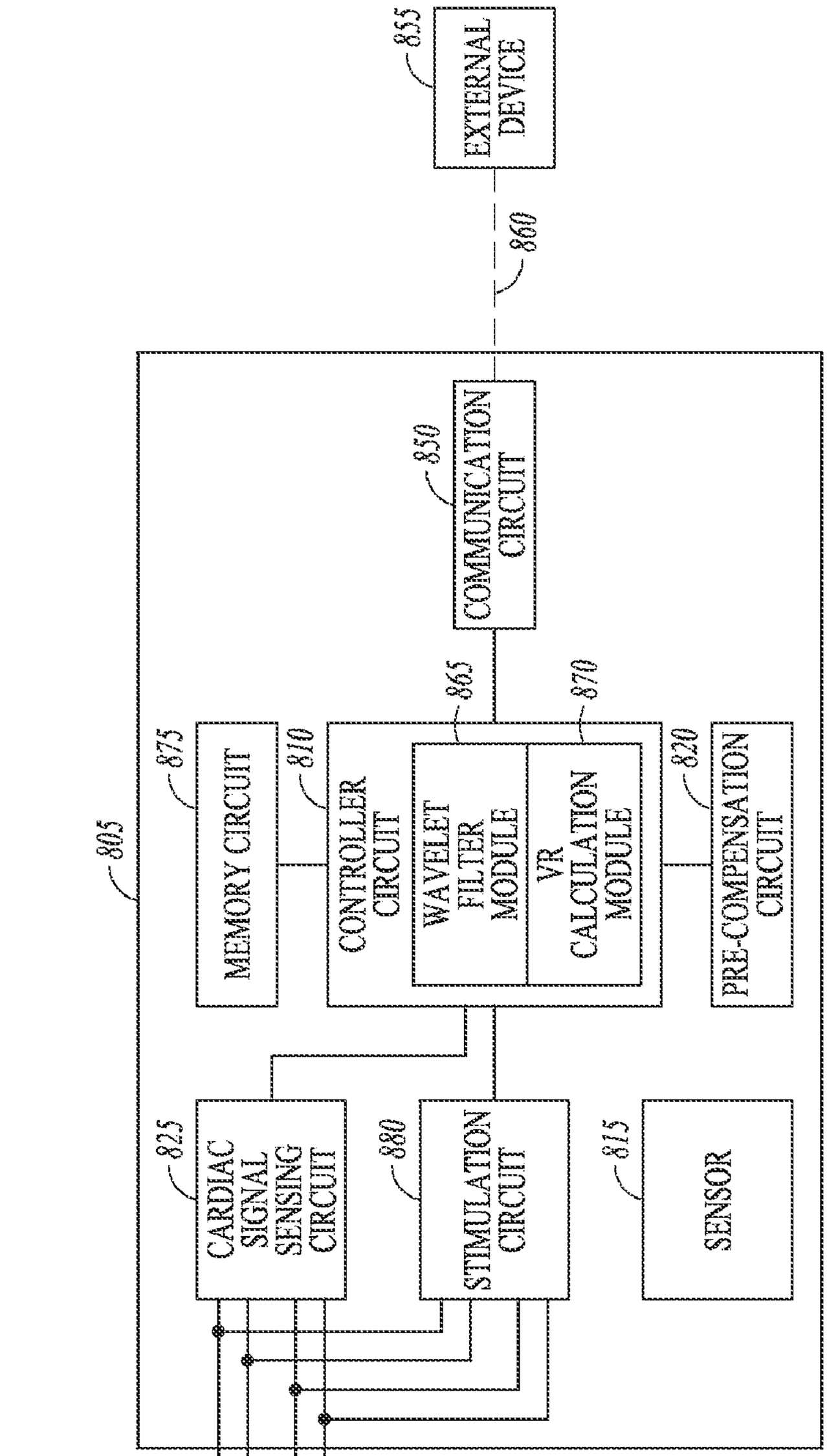
800
805
810
815
820
825
830
835
840
845
850
855
860
865
870
875
880
EXTERNAL DEVICE
COMMUNICATION CIRCUIT
MEMORY CIRCUIT
CONTROLLER CIRCUIT
WAVELET FILTER MODULE
VR CALCULATION MODULE
PRE-COMPENSATION CIRCUIT
CARDIAC SIGNAL SENSING CIRCUIT
STIMULATION CIRCUIT
SENSOR

FIG. 8

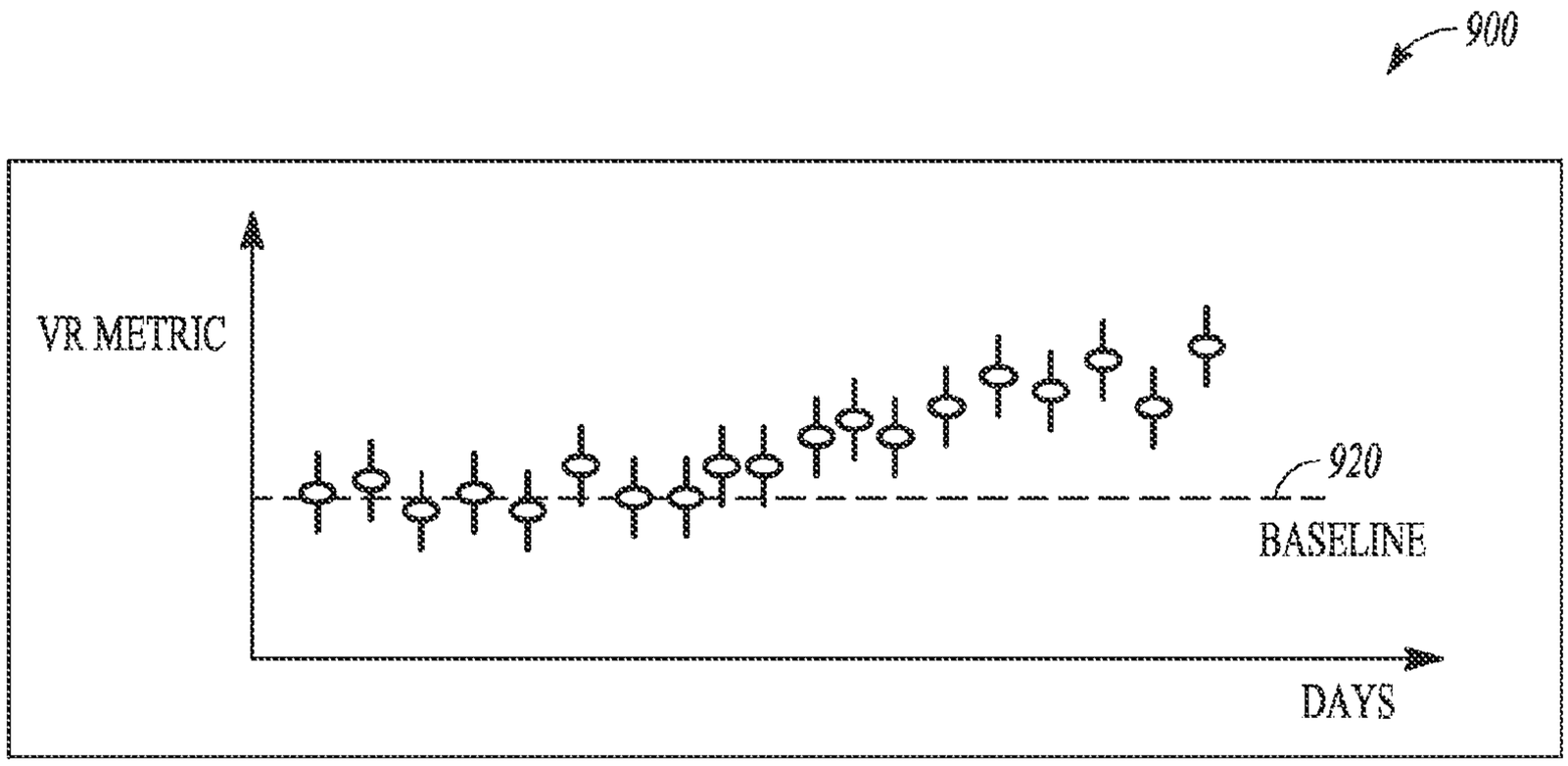
900
VR METRIC
920
BASELINE
DAYS

FIG. 9

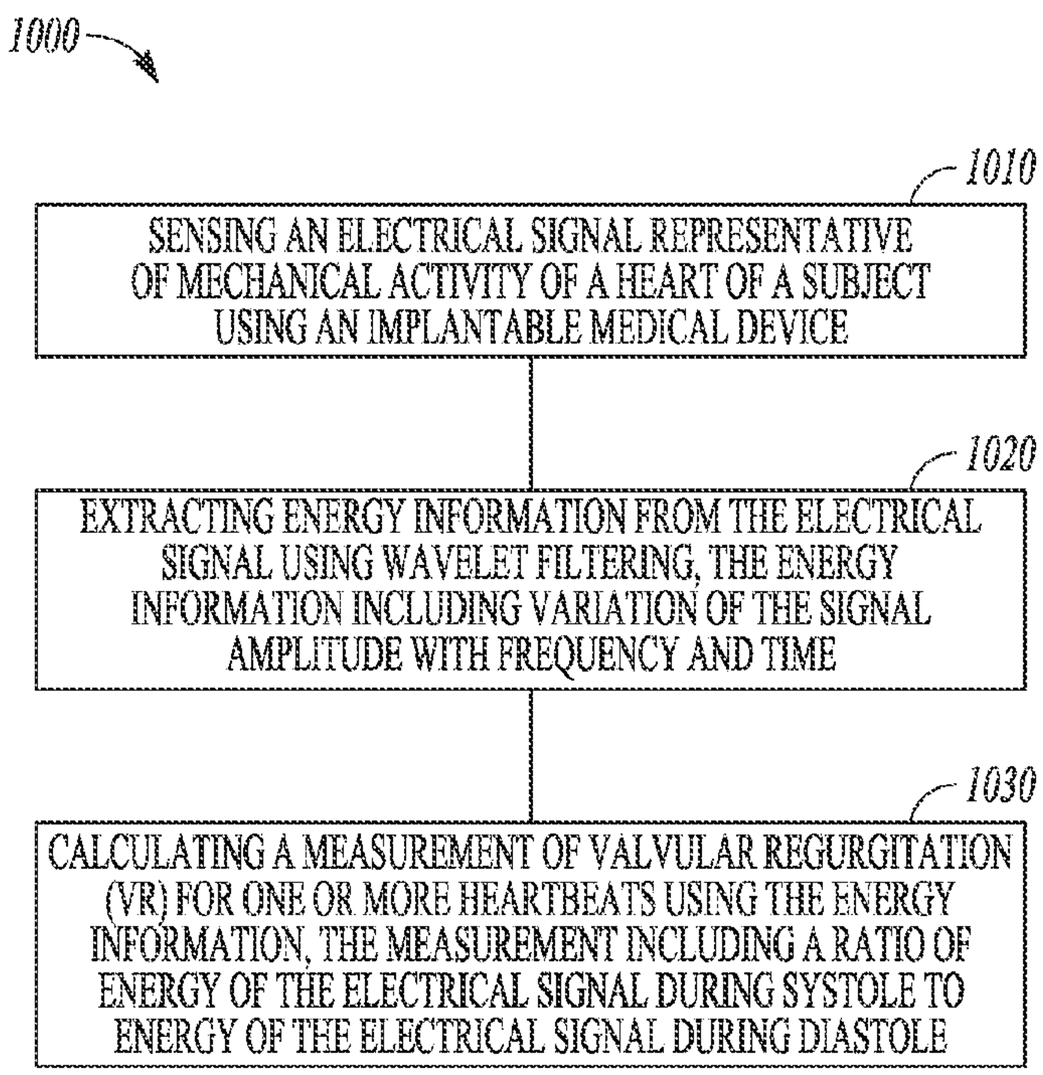
1000
1010
SENSING AN ELECTRICAL SIGNAL REPRESENTATIVE OF MECHANICAL ACTIVITY OF A HEART OF A SUBJECT USING AN IMPLANTABLE MEDICAL DEVICE
1020
EXTRACTING ENERGY INFORMATION FROM THE ELECTRICAL SIGNAL USING WAVELET FILTERING, THE ENERGY INFORMATION INCLUDING VARIATION OF THE SIGNAL AMPLITUDE WITH FREQUENCY AND TIME
1030
CALCULATING A MEASUREMENT OF VALVULAR REGURGITATION (VR) FOR ONE OR MORE HEARTBEATS USING THE ENERGY INFORMATION, THE MEASUREMENT INCLUDING A RATIO OF ENERGY OF THE ELECTRICAL SIGNAL DURING SYSTOLE TO ENERGY OF THE ELECTRICAL SIGNAL DURING DIASTOLE

FIG. 10

SYSTEMS AND METHODS FOR VALVULAR REGURGITATION DETECTION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is related to the following, commonly assigned U.S. Patent Applications: Ser. No. 10/900,570 entitled "DETERMINING A PATIENT'S POSTURE FROM MECHANICAL VIBRATIONS OF THE HEART," filed on Jul. 28, 2004, now issued as U.S. Pat. No. 7,559,901; Ser. No. 10/703,175, entitled "A DUAL USE SENSOR FOR RATE RESPONSIVE PACING AND HEART SOUND MONITORING," filed on Nov. 6, 2003, now issued as U.S. Pat. No. 7,248,923; Ser. No. 10/334,694 entitled "METHOD AND APPARATUS FOR MONITORING OF DIASTOLIC HEMODYNAMICS," filed on Dec. 30, 2002, Ser. No. 10/746,874 entitled "A THIRD HEART SOUND ACTIVITY INDEX FOR HEART FAILURE MONITORING," filed on Dec. 24, 2003, now issued as U.S. Pat. No. 7,115,096; Ser. No. 11/037,275, entitled "METHOD FOR CORRECTION OF POSTURE DEPENDENCE ON HEART SOUNDS," filed on Jan. 18, 2005, now issued as U.S. Pat. No. 7,662,104; Ser. No. 60/631,742 entitled "CARDIAC ACTIVATION SEQUENCE MONITORING FOR ISCHEMIA DETECTION," filed on Nov. 30, 2004, Ser. No. 11/129,050, entitled "METHOD AND APPARATUS FOR CARDIAC PROTECTION PACING," filed on May 16, 2005, and Ser. No. 11/148,107, entitled "ISCHEMIA DETECTION USING HEART SOUND SENSOR," filed on Jun. 8, 2005, each of which is hereby incorporated by reference.

TECHNICAL FIELD

The field generally relates to implantable medical devices and, in particular, but not by way of limitation, to systems and methods for monitoring mechanical activity of the heart.

BACKGROUND

Implantable medical devices (IMDs) are devices designed to be implanted into a patient. Some examples of these devices include cardiac function management (CFM) devices such as implantable pacemakers, implantable cardioverter defibrillators (ICDs), cardiac resynchronization devices, and devices that include a combination of such capabilities. The devices are typically used to treat patients using electrical or other therapy and to aid a physician or caregiver in patient diagnosis through internal monitoring of a patient's condition. The devices may include one or more electrodes in communication with sense amplifiers to monitor electrical heart activity within a patient, and often include one or more sensors to monitor one or more other internal patient parameters. Other examples of implantable medical devices include implantable diagnostic devices, implantable insulin pumps, devices implanted to administer drugs to a patient, or implantable devices with neural stimulation capability.

Blood flows from the left atrium to the left ventricle through the mitral valve during diastole or the filling phase. During systole, the mitral valve is closed and blood is ejected through the aortic valve by the contraction of the left ventricle. A defective or partially closed mitral valve can cause blood to leak and cause turbulence near the mitral annulus. This leakage is called mitral regurgitation (MR). MR can also occur with a normal mitral valve due to a dilated and dyssynchronous left ventricle, which may be caused by cardiovascular disease. Improper atrial-ventricular delay (AV delay) can cause left ventricular dyssynchrony, which can lead to a partially closed mitral valve, in turn causing MR. MR also refers to regurgitation due to mitral stenosis, and mitral valve prolapse.

Blood flows from the right atrium to the right ventricle through the tricuspid valve during diastole. During systole, the tricuspid valve is closed and blood is ejected through the pulmonic valve by the contraction of the right ventricle. A defective or partially closed tricuspid valve can cause blood to leak backward through the tricuspid valve. This leakage is called tricuspid regurgitation (TR). Typically, TR occurs due to a defective tricuspid valve, but can also occur due to cardiac disease. Other forms of regurgitation include aortic regurgitation (AR), which includes regurgitation due to aortic stenosis. Valvular regurgitation (VR) refers to MR, or TR, or AR, or any combination of two or more of MR, TR, and AR. VR can make it difficult for the heart to increase blood flow during times of higher demand, such as during exercise.

It is believed that MR increases with congestive heart failure decompensation. It is also believed that ten percent of MR is caused by ischemia. A mitral valve or tricuspid valve of a heart can become damaged through infection or disease. Certain diet medications have been known to cause valvular damage. Acute MR resulting from myocardial infarction may have sixty to eighty percent mortality if it is present with severe pulmonary edema. Chronic MR may lead to severe left ventricle dysfunction, chronic congestive heart failure, or atrial fibrillation. The present inventors have recognized a need for improved sensing of events related to cardiac activity.

SUMMARY

This document discusses, among other things, systems and methods for monitoring mechanical activity of the heart. A system embodiment includes an implantable medical device (IMD). The IMD includes an implantable sensor operable to produce an electrical signal representative of mechanical activity of a heart of a subject and a controller circuit coupled to the sensor. The controller circuit includes a wavelet filter module and a valvular regurgitation (VR) calculation module. The wavelet filter module is configured to extract signal energy information related to VR from the electrical signal. The energy information includes variation of signal amplitude with frequency and time. The VR calculation module is configured to calculate a measurement of VR for one or more heartbeats using the energy information.

A method embodiment includes sensing an electrical signal representative of mechanical activity of a heart of a subject, extracting energy information from the electrical signal using wavelet filtering, and calculating a measurement of VR for one or more heartbeats using the energy information. The energy information includes a variation of signal amplitude with frequency and time. The VR measurement includes a ratio of energy of the electrical signal representative of VR during systole to energy of the electrical signal during diastole.

This summary is intended to provide an overview of the subject matter of the present patent application. It is not intended to provide an exclusive or exhaustive explanation of the invention. The detailed description is included to provide further information about the subject matter of the present patent application.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a block diagram of portions of a system that uses an implantable medical device.

FIG. **2** illustrates an implantable medical device coupled by one or more leads to a heart.

FIGS. **3**A and **3**B show embodiments of portions of systems that detect VR using implantable medical devices.

FIG. **4** shows a representation of a waveform of an electrical signal provided by a sensor.

FIG. **5** shows a representation of a waveform of an electrical signal provided by a sensor that has been pre-compensated.

FIG. **6** shows graphical representations of the decomposition of the electrical signal obtained from a sensor.

FIG. **7** shows a waveform of an electrical signal provided by a sensor that has been filtered by a wavelet filter.

FIG. **8** shows an embodiment of portions of a system that detects VR using an implantable medical device.

FIG. **9** shows a graph representing trending of VR data.

FIG. **10** shows a block diagram of an embodiment of a method of detecting VR.

DETAILED DESCRIPTION

In the following detailed description, reference is made to the accompanying drawings which form a part hereof, and specific embodiments in which the invention may be practiced are shown by way of illustration. It is to be understood that other embodiments may be used and structural or logical changes may be made without departing from the scope of the present invention.

Valvular regurgitation (VR) is manifested as a turbulent blood flow in the left or right atrium or near the aortic valve during systole. VR refers to mitral regurgitation (MR), or tricuspid regurgitation (TR), or aortic regurgitation (AR), or a combination of two or more of MR, TR, and AR. Some amount of VR is believed present during early systole in eighty percent of patients exhibiting interventricular dyssynchrony between their right and left ventricles. Sensors can be included in implantable medical devices (IMDs) to provide internal patient diagnosis. The output from one or more sensors appropriate to sense mechanical heart activity (in contrast to electrical activity) can be used to provide a measure of VR. Examples of such sensors include those used to detect pressure changes in the heart due to VR or to detect mechanical vibrations of the heart that indicate VR. If the VR is a result of dyssynchrony of the left ventricle, a CFM device can restore proper synchrony, such as by providing or adjusting a proper atrial-ventricular (AV) delay, left ventricular pacing, or biventricular pacing.

FIG. **1** is a block diagram of portions of a system **100** that uses an implantable medical device (IMD) **110**. As one example, the system **100** shown is used to treat a cardiac arrhythmia. The IMD **110** includes an electronics unit coupled by a cardiac lead **108**, or additional leads, to a heart **105** of a patient **102**, or otherwise associated with the heart **105**. Examples of IMD **110** include, without limitation, a pacer, a defibrillator, a cardiac resynchronization therapy (CRT) device, or a combination of such devices. System **100** also typically includes an IMD programmer or other external device **170** that communicates wireless signals **160** with the IMD **110**, such as by using radio frequency (RF) or other telemetry signals.

Cardiac lead **108** includes a proximal end that is coupled to IMD **110** and a distal end, coupled by an electrode or electrodes to one or more portions of a heart **105**. The electrodes typically deliver cardioversion, defibrillation, pacing, or resynchronization therapy, or combinations thereof to at least one chamber of the heart **105**. The electronics unit of the IMD **110** typically includes components that are enclosed in a hermetically-sealed canister or "can." Other electrodes may be located on the can, or on an insulating header extending from the can, or on other portions of IMD **110**, such as for providing pacing energy, defibrillation energy, or both, in conjunction with the electrodes disposed on or around a heart **105**. The lead **108** or leads and electrodes may also typically be used for sensing intrinsic or other electrical activity of the heart **105**.

FIG. **2** illustrates an IMD **110** coupled by one or more leads **108**A-C to heart **105**. Heart **105** includes a right atrium **200**A, a left atrium **200**B, a right ventricle **205**A, a left ventricle **205**B, and a coronary sinus **220** extending from right atrium **200**A. Atrial lead **108**A includes electrodes (electrical contacts, such as ring electrode **225** and tip electrode **230**) disposed in an atrium **200**A of heart **105** for sensing signals, or delivering pacing therapy, or both, to the atrium **200**A. Ventricular lead **108**B includes one or more electrodes, such as tip electrode **235** and ring electrode **240**, for sensing signals, delivering pacing therapy, or both sensing signals and delivering pacing therapy. Sensing and pacing allows the IMD **110** to adjust timing of the chamber contractions. For example, IMD **110** can adjust the timing of ventricular contractions with respect to the timing of atrial contractions delay by sensing a contraction in the right atrium **200**A and pacing the right ventricle **205**A at the desired AV delay time.

Lead **108**B optionally also includes additional electrodes, such as for delivering atrial cardioversion, atrial defibrillation, ventricular cardioversion, ventricular defibrillation, or combinations thereof to heart **105**. Such electrodes typically have larger surface areas than pacing electrodes in order to handle the larger energies involved in defibrillation. Optionally, leads **108**A and **108**B are combined into one lead containing four electrodes located sequentially along the lead. In an example, a first tip electrode is located in the apex of the right ventricle **205**A, a first ring electrode located proximal to the tip electrode and in the right ventricle **205**A, a second ring electrode located proximal to the first ring electrode and in the right atrium **200**A, and a third ring electrode located proximal to the second ring electrode and also located in the right atrium **200**A.

In certain examples, a third cardiac lead **108**C is attached to the IMD **110** through the header **255**. The third lead **108**C typically includes ring electrodes **260** and **265** placed in a coronary vein **220** extending along a wall of the left ventricle (LV) **205**B. Lead **108**B and **108**C optionally provide resynchronization therapy to the heart **105**.

FIGS. **3**A-B show embodiments of portions of systems **300** that detect VR using IMDs. In the embodiment of FIG. **3**A, the IMD **310** includes an implantable sensor **315** coupled to a controller circuit **320**. The implantable sensor **315** produces an electrical signal representative of mechanical activity of a heart. In FIG. **3**A the sensor **315** is located within the can of the IMD **310**. Examples of sensors that produce an electrical signal representative of mechanical activity of the heart of a subject from within an IMD include an accelerometer and a microphone. FIG. **3**B shows a sensor **325** that is placed outside of the can of an IMD **330**. In this example, the sensor **325** includes its own hermetically sealed housing and is coupled to the controller circuit **320**, such as by an electrical lead **335**. Examples of a sensor **325** that produces an electrical signal representative of mechanical activity of the heart which is placed outside of the IMD can include a pressure sensor, microphone, and an accelerometer. The example of the sensor **325** shown represents a pressure sensor on the tip of the electrical lead **335** placed in the coronary sinus **340**. Descriptions of methods and systems for measuring left ventricular pressure are found in U.S. Pat. No. 6,666,826, Salo et al.,

entitled, "Method and Apparatus for Measuring Left Ventricular Pressure," which is hereby incorporated by reference. In other examples, a pressure sensor is placed in the right ventricle, right atrium, or the pulmonary artery.

The controller circuit **320** includes a wavelet filter module **345** and an VR calculation module **350**. The wavelet filter module **345** extracts signal energy information from the electrical signal output by the implantable sensor **315** or **325**. Wavelet analysis decomposes an electrical signal with both frequency and time. Therefore, the signal energy information includes variations of the amplitude of the electrical signal with both frequency and time.

Wavelet analysis overcomes a fundamental shortcoming of Fourier analysis. When an electrical signal is analyzed over a finite length of time, two problems can result. The first problem is time localization. Because the shape of the electrical signal waveform is highly dependent on the window of time used to sample the electrical signal, a window that is too long in time can cause localized time information in the electrical signal to be overlooked due to too much data or due to undersampling of the signal. The second problem is frequency localization. If the window is too short there may be too few oscillations to determine localized frequency information in the electrical signal. Fourier analysis can be viewed as representing a signal as a sum of sinusoidal waves. These sinusoids are well localized in frequency, but not in time. Thus, Fourier analysis can only show the frequency (spectral) information of the time signal analyzed.

One possibility for Fourier analysis would be to implement a windowed (or running) Fourier transform (short-time Fourier transform, or STFT). STFT uses a certain window size and slides it along the signal in time, computing the FFT at each time using only the data within the window, thereby producing a series of FFT transforms. However, the results are still dependent on the window size used. The main problem with the STFT is the inconsistent treatment of different frequencies; at low frequencies there so few oscillations within the window that it is not possible to extract localized frequency information, while at high frequencies there are so many oscillations that localized time information is lost. Additionally, the STFT still relies on the assumption that the signal can be decomposed into sinusoidal components.

In wavelet analysis, a scalable modulated window is typically shifted along the time domain electrical signal and for every position the frequency spectrum is calculated. This process is typically repeated many times with a slightly shorter (or longer) window for every new cycle of the electrical signal. By using a variable width window, wavelet analysis effectively zooms in on the signal when analyzing higher frequencies, thus providing higher resolution when necessary. The result is a collection of time-frequency representations of the signal having different resolutions.

FIG. **4** shows a representation of a waveform **400** of an electrical signal provided by a sensor to the wavelet filter **345**. Because the sensor in this case was an accelerometer, the waveform **400** is an electrical signal that represents vibrations, including vibrations from the occurrence of VR. In certain examples, the bandwidth of the accelerometer is 0-500 hertz (Hz), i.e., at 500 Hz, the response of the accelerometer is twenty decibels (db) down from its highest response. In an example, an electrical signal output from an accelerometer is obtained by sampling the sensor output at 1000 Hz with twelve-bit quantization.

Some sensors have a low frequency response, i.e., the response of the sensors rolls off or is attenuated with higher frequencies. Such roll-off may be due to a transfer function of the sensor itself or from the interface between the sensor and human tissue. Electrical signals of interest in detecting VR may have frequency components where the sensor response is attenuated, such as from 100-500 Hz for example. For this reason, some embodiments include a pre-compensation circuit to compensate for such roll-off before the signal is processed by the wavelet filter module **345** of FIGS. **3**A-B. The pre-compensation circuit is coupled between the sensor **315** or **325** and the controller circuit **320**. An example of a pre-compensation circuit is an inverse filter circuit having high frequency gain, such as a high pass circuit having a response matched to a low pass response of a sensor or a sensor/tissue interface. Another example is a digital signal processor that adds high frequency gain to an electrical signal. FIG. **5** shows a waveform **500** that is a representation of the waveform in FIG. **4** after pre-compensation. Note that the signal **500** contains high frequency noise terms.

Many different wavelet functions can be used to decompose the input electrical signal into component parts. In some examples, Daubechies wavelets are used. The ability of a wavelet function to decompose a signal into its component parts depends on how closely the wavelet used approximates the electrical signal. FIG. **6** shows graphical representations **600** of the decomposition of the electrical signal obtained from the sensor. A pre-compensated electrical signal **610** is shown in the top graph. In this example, the decomposition is performed by running the electrical signal through a bank of bandpass filters corresponding to the Daubechies wavelets to obtain the six individual decomposed element signals a**5**, d**5**, d**4**, d**3**, d**2**, and d**1**. In some examples, after the electrical signal **610** is decomposed into component signals, a filtered signal could be obtained by multiplying the decomposed signals by corresponding coefficients to weight the individual decomposed signals. Adding the weighted signals back together provides the filtered signal. A weighting coefficient of zero will eliminate a corresponding signal from the filtered signal result.

FIG. **7** shows a waveform **700** of the wavelet filtered signal **710** output by the wavelet filter module **345** in FIGS. **3**A-B in response to the pre-compensated signal **500** of FIG. **5**. In certain examples, the VR calculation module **345** of FIGS. **3**A-B is configured to calculate a measurement of VR for one or more heartbeats using signal intensity information of the wavelet filtered signal. The measurement typically includes a ratio of the energy of the electrical signal during systole **720** to the energy of the electrical signal during diastole **730**. The energy of the electrical signal during systole typically is calculated by summing the samples during a heart contraction. The intensity in the signal during diastole is typically calculated by summing the samples during a heart expansion. This leads to the ratio VR metric:

$$\text{Ratio } VR \text{ Metric} = \frac{\sum_{i=1}^{m} |C_b(K+i)|}{\sum_{j=1}^{n} |C_b(K'+j)|}, \tag{1}$$

where K and K' are the beat index for systole and diastole respectively, m is the number of samples taken during systole, n is the number of samples taken during diastole, i and j are variables corresponding to the sample number, and C_b corresponds to a measure of energy at that sample. An example of a measure of energy at a sample would be the amplitude of the signal. Another example would be the power of the signal.

In some examples, the ratio VR metric can be calculated on a per-beat basis. In FIG. **7**, the ratio VR metric is calculated on

the K,K' index beat by summing m samples taken during systole **720** and summing n samples taken during diastole **730**. In some examples, n and m are the same integer number. For example, fifty samples could be collected during systole and fifty samples could be collected during diastole. Because the absolute value is used in equation 1, samples at signal peaks **725** and **727** are additive and result in a greater sum during systole **720** than a sum of samples including signal peaks **735** and **737** during diastole **730**. In some examples, the resulting ratio VR metric is compared to a ratio VR metric threshold value and VR is declared when the measured ratio VR metric exceeds the ratio VR metric threshold value.

In some examples, the ratio VR metric is calculated over a specified number of beats. In an example where the ratio VR metric is calculated over three beats, in FIG. **7** the ratio VR metric is calculated over the K−1,K'−1 index beat **740** (partially shown), the K,K' index beat **720**, **730**, and the K+1,K'+1 index beat **750** (partially shown). In another example, the ratio VR metric is calculated over ten beats. In some examples, the total ratio VR metric calculated over the specified number of beats is compared to a ratio VR metric threshold value to declare VR. In some examples, a per-beat central tendency of the ratio VR metric calculated over the specified number of beats is compared to a ratio VR metric threshold value to declare VR.

Other VR metrics are possible. In an example, a measurement of VR includes the difference between the energy of the electrical signal during systole and the energy of the electrical signal during diastole. i.e.,

$$\text{Difference } VR \text{ metric} = \sum_{i=1}^{m} |C_b(K+i)| - \sum_{j=1}^{n} |C_b(K'+j)|. \quad (2)$$

In some examples, the electrical signal provided by the sensor is used to identify or help identify systole and diastole. For example, the peak amplitude **405** of the accelerometer waveform of FIG. **4** indicates the start of systole. In some examples, one or more additional signals obtained by the system **300** are used to identify or help identify systole or diastole. In some examples, the system **300** further includes cardiac signal sensing circuits coupled to the controller circuit **320** and to electrodes located in association with the heart to detect one or more cardiac signals related to heart contractions. Cardiac signal artifacts such as P-waves (from atrial contractions) and R-waves (from ventricular contractions) are then correlated with the wavelet filtered signal to identify or help identify systole and diastole.

In some examples, heart sounds are additionally or alternatively correlated with the wavelet filtered signal to identify systole or diastole. Heart sounds are associated with mechanical vibrations from activity of a patient's heart and the flow of blood through the heart. Heart sounds recur with each cardiac cycle and are separated and classified according to the activity associated with the vibration. The first heart sound (S**1** in FIG. **7**) is the vibrational sound made by the heart during tensing of the mitral valve. The second heart sound (S**2** in FIG. **7**) marks the beginning of diastole. The heart sounds can be sensed using the same sensor that is used to detect VR or an additional sensor. Examples of sensors that can detect heart sounds include an accelerometer or a microphone.

The VR metric can be used to monitor VR for changes or incidents of VR. A wide variety of statistical methods can be used. In some embodiments, the controller circuit **320** of FIG. **3**A-B merely keeps track of a count of VR events that exceed an VR metric threshold value. In some embodiments, the controller circuit **320** includes a central tendency computation module. The central tendency module calculates a central tendency of VR measurements, such as a running average for example, over a specified number of heartbeats.

In some examples, the systems **300** include memory circuits to store a trend or other information related to VR. In some examples, the system **300** includes a communication circuit coupled to the controller circuit **320** to wirelessly communicate information related to VR to an external device. In some examples, the external device contains the wavelet filter module or VR calculation module. The controller circuit **320** transmits to an external device sample values of the electrical signal obtained from the sensor or from a pre-compensated signal. The external device performs the wavelet filtering or the measurement of VR.

FIG. **8** shows an embodiment of portions of a system **800** that detects VR using an IMD **805**. The IMD **805** includes a controller circuit **810** and a sensor circuit **815**. The sensor **815** produces an electrical signal representative of mechanical activity of a heart. In some examples, the sensor is within the IMD can. In some examples, the sensor includes its own hermetically sealed housing, is placed outside of the can of the IMD **805**, and is connected to the IMD **805**, such as by an implantable lead. In some examples, the sensor **815** includes an accelerometer. In some examples, the sensor **815** includes an implantable microphone. In some examples the sensor includes an implantable pressure sensor. The IMD **805** further includes a pre-compensation circuit **820** coupled between the controller circuit **810** and the sensor **815**.

The IMD **805** further includes a cardiac signal sensing circuit **825** coupled to the controller circuit **810** and is configured to provide electrical signals representative of cardiac activity. In certain examples, the cardiac signal sensing circuit is coupled to one or more electrodes such as by one or more cardiac leads to tip electrodes **830**, **840** and ring electrodes **835**, **845**. In some embodiments, the electrodes **830**, **835** are configured to sense one or more cardiac signals of a right atrium and electrodes **840**, **845** are configured to sense one or more cardiac signals of a right ventricle. In some embodiments, the electrodes **830**, **835** are configured to sense one or more cardiac signals of a right ventricle and electrodes **840**, **845** are configured to sense one or more cardiac signals of a left ventricle. The IMD **805** further includes a communication circuit **850** that communicates one or more wireless signals **860** with external device **855**.

In some examples, the IMD **805** includes a wavelet filter module **865** and VR calculation module **870**. The wavelet filter module **865** extracts signal energy information from the electrical signal output by the sensor **815**, the energy information including variation of the signal amplitude with frequency and time. The VR calculation module **870** calculates a measurement of VR for one or more heartbeats using the energy information. Measurements of VR are stored in memory circuit **875**. In certain examples, the VR measurement includes a ratio of energy of the electrical signal obtained from the sensor during systole to energy of the electrical signal obtained during diastole. The IMD **805** communicates information related to VR to the external device **855**.

In some examples, the wavelet filter module **865** or VR calculation module **870** are included in the external device **855**. The controller circuit **810** transmits the electrical signal obtained from the sensor **815** to the external device **855**. The wavelet filtering or the calculation of the VR measurement is

done in the external device **855**. In some examples, the controller circuit **810** transmits a pre-compensated signal to the external device **855**.

The IMD **805** further includes a stimulation circuit **880** coupled to the controller circuit **320** and cardiac electrodes. In some examples, the stimulation circuit **880** provides cardiac resynchronization therapy (CRT) to the heart. The controller circuit **810** initiates, terminates, or otherwise adjusts at least one stimulation parameter related to CRT, such as to reduce an amount of VR indicated by the measurement of VR, either alone or in combination with some other goal. In some examples, the cardiac leads and electrodes **830**, **835**, **840**, **845** are configured to sense cardiac signals and provide CRT to the left and right ventricles. The controller circuit **810** is operable to adjust an interventricular delay between sensing or pacing a right ventricle and a left ventricle during the same cardiac cycle to reduce an amount of VR. In some examples, the cardiac leads and electrodes **830**, **835**, **840**, **845** are configured to sense cardiac signals and provide pacing therapy to the atrium and ventricle. The controller circuit **810** is operable to adjust an A-V delay between pacing the atrium and the ventricle during the same cardiac cycle to reduce an amount of VR, either alone or in combination with some other goal. In some examples, the wavelet filter module **865** and VR calculation module **870** are included in the controller circuit **810** and controller circuit **810** calculates the adjustment to the stimulation parameter.

In some examples, the wavelet filter module **865** and VR calculation module **870** are included in the external device **855** and the external device **855** calculates the adjustment to the stimulation parameter and programs one or more parameters into the IMD **805**. In some embodiments, the external device **855** is a local or remote IMD programmer and includes a display and presents one or more suggested stimulation parameters to a care giver who then optionally selects particular suggested parameters or selects different desired values for such parameters to be programmed into the IMD **805**.

In some examples, the IMD **805** or the external device **855** uses VR information to trend VR for a patient. FIG. **9** shows a graph **900** representing trending of VR data by the external device **855**. Data points **910** of VR measurements are used to calculate a baseline measurement value **920**. If the data trending indicates an increase in the VR measurement (e.g., beyond a specified threshold), the external device **855** is operable to communicate an alarm indicating increased VR. This increase that causes an alarm to be indicated can be a sustained increase over time or a measurement that crosses a threshold VR value. In some examples, the alarm is a visual alarm on a display. In some examples, the alarm is an audible alarm. In some examples, the external device **855** is connected to a network and the alarm is indicated over the network. In some examples, the network includes a computer network such as a hospital network or the internet. In some examples the external device **855** is in communication with a server that is connected to a network. In some examples, the server includes memory, a processor, and a wavelet filter module and the VR calculation module. The server trends measurements of VR and the alarm indication originates from the server. In some examples, the network includes a mobile phone network. In some examples, the alarm is communicated from the IMD **805**.

In certain examples, external device **855** provides an indication of heart failure (HF) decompensation. Because it is believed that VR increases with HF decompensation, the external device **855** uses the VR information to provide an indication of HF decompensation. In some examples, the indication of HF decompensation uses the information related to VR in addition to information related to at least one other measured physiologic parameter. Examples of these other measured physiologic parameters include intracardiac impedance, at least one heart sound, and patient respiration.

FIG. **10** shows a block diagram of an embodiment of a method **1000** of detecting VR. At **1010**, an electrical signal representative of mechanical heart activity of a subject is sensed using an implantable medical device (IMD). The electrical signal is provided by an implantable sensor that converts the mechanical activity into the electrical signal. Examples of such a sensor appropriate to sense mechanical activity related to VR include an accelerometer, a pressure sensor, and a microphone. For some sensors, the magnitude of the electrical signal provided rolls off with higher frequencies. In these cases, the method **1000** may further include compensating for this frequency response.

At **1020**, energy information is extracted from the electrical signal using wavelet filtering. This energy information includes the variation of the signal amplitude with frequency and time. In some examples, the wavelet filtering uses Daubechies wavelets to decompose the electrical signal into its component signals. The component signals are multiplied by corresponding weighting coefficients to perform the filtering and are then recombined to obtain the wavelet filtered signal.

In some examples, wavelet filtering is done by a controller circuit, such as a processor, in the IMD. In some examples, a sampled electrical signal from the sensor, or a sampled electrical signal that has been pre-compensated, is communicated to an external device. In some examples, the external device then performs the wavelet filtering. An example of such an external device is an IMD programmer that communicates wirelessly with the IMD. In some examples, the external device transmits the sampled signal information to third device over a network and the third device performs the wavelet filtering. An example of such an external device is a computer in communication with a network and an example of the third device is a server. In another example, the external device is a repeater that communicates wirelessly with the IMD and with a third device in communication with a network, such as a computer network or mobile telephone network. The wavelet filtering can be performed by any device on the network that can receive the sampled signal information and contains a processor executing instructions to perform the wavelet filtering. An example of such a device is a server connected to the network.

At **1030**, a measurement of VR is calculated for one or more heartbeats using the energy information. In certain examples, the VR measurement includes a ratio of the energy of the electrical signal during systole to the energy of the electrical signal during diastole. Typically it is more convenient for the device that performs the wavelet filtering (either an IMD or an external device) to also calculate the VR measurement from the wavelet filtered signal, but this is not strictly necessary. A digital representation of the wavelet filtered signal could be communicated to another device to calculate the VR measurement.

In some examples, an additional physiologic parameter is used to help identify systole and diastole in the wavelet filtered signal. Examples of the additional physiologic parameter include an electrogram (egram) of intrinsic electrical heart activity internally sensed, such as with the IMD, or heart sounds sensed with the IMD using the same or a different sensor used to provide the electrical signal representative of mechanical activity of a heart. In some examples, the method **1000** further includes calculating a central tendency of the measurement of VR over a predetermined number of beats.

Examples of a central tendency calculation include an average value and a median value of the VR measurement.

One cause of VR is dyssynchrony of contractions of the chambers of the heart. For this reason, some examples of the method **1000** include adjusting a stimulation parameter related to cardiac resynchronization therapy (CRT) to reduce an amount of VR indicated by the measurement of VR. An example of adjusting a stimulation parameter includes adjusting an A-V delay between sensing or pacing an atrium and pacing a ventricle during the same cardiac cycle in order to provide proper atrial-ventricular synchrony. Another example includes adjusting an interventricular delay between sensing or pacing a right ventricle (RV) and a left ventricle (LV) during the same cardiac cycle to provide proper RV-LV synchrony. Another example includes selecting a different vector or set of vectors to provide cardiac resynchronization therapy (CRT). The term "vector" refers to a combination of electrodes. If the electrodes are used to sense electrical signals, sensing among different sets of electrodes, or vectors, often provides directional information regarding the propagation of cardiac signals. Choosing a different vector to deliver therapy often provides a different area to deliver the therapy, a different direction to provide the therapy, or a different timing relationship among the possible combinations. The adjustment of the stimulating parameter can originate from the external device or the IMD. If adjustments to CRT parameters are made by the IMD based on VR calculations made by the IMD, the VR measurement and the CRT stimulation can form a closed loop feedback system such as to reduce or minimize VR in the heart.

It is desirable for a care giver to monitor changes in VR. For this reason, some examples of the method **1000** further include trending the measurement of VR over time. The trending can be done by either an IMD or an external device. A baseline VR measurement is calculated. Deviations from the baseline that are more than a specified threshold deviation cause the device to provide an indication of increased VR. An example of such an indication is an audible alarm provided by the IMD. Another example is a visual indication on a display provided by the external device. In some examples, the trending of the VR measurement over time is displayed on the external device. Trending is useful not only to monitor progress of VR but also to monitor how a patient responds to CRT. If one or more parameters related to CRT are changed, the responsiveness of the patient to the change can be measured by tracking the measurement of VR.

Because VR is believed to increase with HF decompensation, some examples of the method **1000** further include providing an indication of heart failure decompensation using the VR measurement. A sudden increase in VR indicated by the VR measurement can be caused by an HF decompensation event occurring or by a worsening condition of HF. In some examples, the VR measurement is combined with at least one other measured physiologic parameter to provide an indication of HF decompensation. This is useful if the VR measurement is needed to confirm HF decompensation indicated by the other measured physiologic parameter. Some examples of the other measured physiologic parameter include intracardiac impedance, amplitude of heart sounds, and patient respiration.

The systems and methods described herein may be used to detect other events related to cardiac activity in addition to VR, such as additional forms of heart murmurs. Use of a specific embodiment of the systems and methods may depend on particular placement of the sensor or sensors or may depend on the type of signature the cardiac event provides. For example, a specific type of cardiac event may be more readily detected and measured by using a different set of wavelets in the filtering.

The accompanying drawings that form a part hereof, show by way of illustration, and not of limitation, specific embodiments in which the subject matter may be practiced. The embodiments illustrated are described in sufficient detail to enable those skilled in the art to practice the teachings disclosed herein. Other embodiments may be utilized and derived therefrom, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. This Detailed Description, therefore, is not to be taken in a limiting sense, and the scope of various embodiments is defined only by the appended claims, along with the full range of equivalents to which such claims are entitled.

Such embodiments of the inventive subject matter may be referred to herein, individually and/or collectively, by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept if more than one is in fact disclosed. Thus, although specific embodiments have been illustrated and described herein, it should be appreciated that any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations, or variations, or combinations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

The Abstract of the Disclosure is provided to comply with 37 C.F.R. §1.72(b), requiring an abstract that will allow the reader to quickly ascertain the nature of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims. In addition, in the foregoing Detailed Description, it can be seen that various features are grouped together in a single embodiment for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the claimed embodiments require more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive subject matter lies in less than all features of a single disclosed embodiment. Thus the following claims are hereby incorporated into the Detailed Description, with each claim standing on its own.

What is claimed is:

1. A system comprising:

an implantable medical device (IMD) comprising:

an implantable sensor operable to produce an electrical signal representative of mechanical activity of a heart of a subject; and

a controller circuit coupled to the sensor, wherein the controller circuit includes:

a wavelet filter module including a wavelet filter, the wavelet filter module, configured to:

generate a set of time-frequency representations of the electrical signal; and

produce a wavelet filtered electrical signal using the set of time-frequency representations; and

a valvular regurgitation (VR) calculation module configured to calculate a measurement of VR for one or more heartbeats using a measurement of systolic energy of the wavelet filtered electrical signal during systole and a measurement of diastolic energy of the wavelet filtered electrical signal during diastole.

2. The system of claim 1, wherein the measurement of VR includes a ratio of energy of the electrical signal during systole to energy of the electrical signal during diastole.

3. The system of claim 1, wherein the measurement of VR includes a difference of energy of the electrical signal during systole to energy of the electrical signal during diastole.

4. The system of claim 1, further including a pre-compensation circuit coupled to the sensor and the controller circuit, the pre-compensation circuit including a frequency response to compensate for the frequency response of the sensor.

5. The system of claim 1, wherein the controller circuit further includes a central tendency computation module to calculate a central tendency of VR measurements over a specified number of heartbeats.

6. The system of claim 1, wherein the IMD further includes a stimulation circuit coupled to the controller circuit, the stimulation circuit to provide cardiac resynchronization therapy (CRT) to the heart, and wherein the controller circuit is operable to adjust at least one stimulation parameter related to CRT to reduce an amount of VR indicated by the measurement of VR.

7. The system of claim 6, wherein the controller circuit is operable to adjust an A-V delay between pacing an atrium and a ventricle during the same cardiac cycle to reduce an amount of VR.

8. The system of claim 6, wherein the controller circuit is operable to adjust an interventricular delay between pacing a right ventricle and a left ventricle during the same cardiac cycle to reduce an amount of VR.

9. The system of claim 1, wherein the IMD further includes a communication circuit coupled to the controller circuit, and wherein the system further includes an external device operable to communicate with the IMD to obtain information related to VR.

10. The system of claim 9, wherein the external device is in communication with a network.

11. The system of claim 9, wherein the external device is operable to communicate an alarm indicating increasing VR.

12. The system of claim 9, wherein the external device includes an indication of heart failure (HF) decompensation that uses the information related to VR.

13. The system of claim 12, wherein the indication of HF decompensation uses the information related to VR in addition to information related to at least one other measured physiologic parameter.

14. The system of claim 13, wherein the physiologic parameter is selected from the group consisting of:
- intracardiac impedance;
- at least one heart sound; and
- patient respiration.

15. The system of claim 1, wherein the implantable sensor includes an implantable accelerometer.

16. The system of claim 1, wherein the implantable sensor includes an implantable pressure sensor.

17. The system of claim 1, wherein the implantable sensor includes an implantable microphone.

18. A system comprising:
- an implantable medical device (IMD) comprising:
  - an implantable sensor operable to produce an electrical signal representative of mechanical activity of a heart of a subject;
  - a sampling circuit coupled to the sensor circuit to produce digital representations of the electrical signal;
  - a communication circuit; and
  - a controller circuit coupled to the communication circuit and the sampling circuit, the controller circuit operable to communicate the digital representations; and
- an external device comprising:
  - a communication circuit operable to communicate information with the IMD, the information including the digital representations;
  - a processor coupled to the communication circuit, the processor including:
    - a wavelet filter module including a wavelet filter, the wavelet filter module configured to:
      - generate a set of time-frequency representations of the electrical signal; and
      - produce a wavelet filtered electrical signal using the set of time-frequency representations; and
    - a valvular regurgitation (VR) module configured to calculate a measurement of VR for one or more heartbeats using a ratio of a measurement of systolic energy of the wavelet filtered electrical signal during systole to a measurement of diastolic energy of the wavelet filtered electrical signal during diastole.

19. The system of claim 18, wherein the external device includes an IMD programmer and the IMD further includes a stimulation circuit coupled to the controller circuit, the stimulation circuit to provide cardiac resynchronization therapy (CRT) to the heart, and wherein the IMD programmer is operable to adjust at least one stimulation parameter in the IMD related to CRT to reduce an amount of VR indicated by the measurement of VR.

20. The system of claim 19, wherein the IMD programmer is operable to adjust an A-V delay between pacing an atrium and a ventricle during the same cardiac cycle to reduce an amount of VR.

21. The system of claim 19, wherein the IMD programmer is operable to adjust an interventricular delay between pacing a right ventricle and a left ventricle during the same cardiac cycle to reduce an amount of VR.

22. The system of claim 18, wherein the external device is in communication with a server, the server connected to a network, the server including memory, the server operable to trend measurements of VR.

23. The system of claim 22, wherein the server includes an indication of heart failure (HF) decompensation that uses the information related to VR.

24. The system of claim 23, wherein the indication of HF decompensation uses the information related to VR in addition to information related to at least one other measured physiologic parameter to provide an indication of heart failure decompensation, wherein the physiologic parameter is selected from the group consisting of:
- intracardiac impedance;
- amplitude of at least one heart sound; and
- patient respiration.

25. The system of claim 22, wherein the server is operable to provide an alarm indicating heart failure decompensation.

26. A method comprising:
- sensing an electrical signal representative of mechanical activity of a heart of a subject using an implantable medical device;
- generating a set of time-frequency representations of the electrical signal
- producing a wavelet filtered electrical signal using the set of time-frequency representations; and
- calculating a measurement of valvular regurgitation (VR) for one or more heartbeats using a ratio of a measurement of systolic energy of the wavelet filtered electrical signal during systole to a measurement of diastolic energy of the wavelet filtered electrical signal during diastole.

27. The method of claim 26, wherein obtaining an electrical signal includes compensating for a sensing frequency response.

28. The method of claim 26, further including calculating a central tendency of the measurement of VR over a predetermined number of beats.

29. The method of claim 26, wherein the method further includes adjusting a stimulation parameter related to cardiac resynchronization therapy (CRT) to reduce an amount of VR indicated by the measurement of VR.

30. The method of claim 29, wherein adjusting a stimulation parameter related to CRT includes adjusting an A-V delay between pacing an atrium and a ventricle during the same cardiac cycle.

31. The method of claim 29, wherein adjusting a pacing parameter related to CRT includes adjusting an interventricular delay between pacing a right ventricle and a left ventricle during the same cardiac cycle.

32. The method of claim 26, further including trending the measurement of VR and displaying the trending over time.

33. The method of claim 26, further including providing an indication of heart failure decompensation using the VR measurement.

34. The method of claim 33, wherein providing an indication of heart failure decompensation using the VR measurement includes using the VR measurement in combination with at least one other measured physiologic parameter.

35. The method of claim 34, wherein the measured physiologic parameter is selected from the group consisting of:

intracardiac impedance;

amplitude of heart sounds; and

patient respiration.

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